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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/943,123 | 08/30/2001 | Yie-Hwa Chang | 16153-8007 | 9303 |

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| EXAMINER |
|---|
| DAVIS, MINH TAM B |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | 9 |

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Applicati n No. | Applicant(s) | |
|---|---|---|---|
| | 09/943,123 | CHANG ET AL. | |
| | Examiner | Art Unit | |
| | MINH-TAM DAVIS | 1642 | |

*-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

It is noted that claims 22-31 were misnumbered and have been renumbered as claims 21-30, according to rule 126.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-5. Claims 1-5, drawn to a variant polypeptide of type 2 methionine aminopeptidase (MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, classified in class 530, subclass 350. Each sequence constitutes a single invention and not a species.

Groups 6-9. Claims 6-15, drawn to a polynucleotide of SEQ ID NO: 9, 10, 11 or 18, encoding SEQ ID NO:6, 7, 8, 16, and a vector containing said polynucleotide, classified in class 536, subclass 23.1. Each sequence constitutes a single invention and not a species.

Groups 10-14. Claims 16-19, drawn to a method for treating fungal infection, comprising administering a variant polypeptide of type 2 methionine aminopeptidase (MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, classified in class 514, subclass 2. Each method of treatment using each sequence constitutes a single invention and not a species.

Groups 15-19. Claims 16-19, drawn to a method for treating cell proliferation, comprising administering a variant polypeptide of type 2 methionine aminopeptidase

(MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, classified in class 514, subclass 2. Each method of treatment using each sequence constitutes a single invention and not a species.

Groups 20-24. Claims 16-19, drawn to a method for treating angiogenesis, comprising administering a variant polypeptide of type 2 methionine aminopeptidase (MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, classified in class 514, subclass 2. Each method of treatment using each sequence constitutes a single invention and not a species.

Groups 25-29. Claims 16-19, drawn to a method for treating a disease mediated by decreased function of p53, comprising administering a variant polypeptide of type 2 methionine aminopeptidase (MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, classified in class 514, subclass 2. Each method of treatment using each sequence constitutes a single invention and not a species.

Group 30-34. Claims 16-19, drawn to a method for treating a disease mediated by immune system activity, comprising administering a variant polypeptide of type 2 methionine aminopeptidase (MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, classified in class 514, subclass 2. Each method of treatment using each sequence constitutes a single invention and not a species.

Groups 35-39. Claims 20-24, drawn to a method for treating fungal infection, comprising administering a polynucleotide encoding a variant polypeptide of type 2 methionine aminopeptidase (MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, classified in class 514, subclass 44. Each method of treatment using each sequence constitutes a single invention and not a species.

Groups 40-44. Claims 20-24, drawn to a method for treating cell proliferation, comprising administering a polynucleotide encoding a variant polypeptide of type 2 methionine aminopeptidase (MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, classified in class 514, subclass 44. Each method of treatment using each sequence constitutes a single invention and not a species.

Groups 45-49. Claims 20-24, drawn to a method for treating angiogenesis, comprising administering a polynucleotide encoding a variant polypeptide of type 2 methionine aminopeptidase (MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, classified in class 514, subclass 44. Each method of treatment using each sequence constitutes a single invention and not a species.

Groups 50-54. Claims 20-24, drawn to a method for treating a disease mediated by decreased function of p53, comprising administering a polynucleotide encoding a variant polypeptide of type 2 methionine aminopeptidase (MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein

the histidine at position 231 is replaced with alanine, classified in class 514, subclass 44. Each method of treatment using each sequence constitutes a single invention and not a species.

Groups 55-59. Claims 20-24, drawn to a method for treating a disease mediated by immune system activity, comprising administering a pollynucleotide encoding a variant polypeptide of type 2 methionine aminopeptidase (MetAP2) that has dominant negative MetAP2 activity, comprising SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, classified in class 514, subclass 44. Each method of treatment using each sequence constitutes a single invention and not a species.

Group 60. Claims 25, 28, drawn to a method for identifying an agent that modulates the activity of MetAP2, using a cell that contains a functional gene that encodes a MetAP2, and wherein said cell does not contain an operable naturally occurring chromosomal copy of a gene encoding a MetAP1, classified in class 435, subclass 4.

Group 61. Claim 26, drawn to a method for identifying an agent that modulates the activity of MetAP2, using a yeast cell which comprises a gene encoding MetAP1 operably linked to a regulatory promoter, classified in class 435, subclass 4.

Groups 62. Claim 27, drawn to a method for identifying an agent that modulates the activity of MetAP2, using a mammalian cell which comprises a gene encoding MetAP1 and a gene encoding a fluorescent protein, classified in class 435, subclass 4.

Groups 63-67. Claims 29-30, drawn to a method for identifying effectors of MetAP2 activity, using a yeast cell that comprises a functional gene that encodes a MetAP2 and a polynucleotide that encodes a dominant negative MetAP2, of SEQ ID NO:6, 7, 8, 16 or SEQ ID NO:12 wherein the histidine at position 231 is replaced with alanine, and wherein said yeast cell does not contain an operable naturally occurring chromosomal copy of a gene encoding a MetAP1, classified in class 435, subclass 4.. Each method of treatment using each sequence that encodes a single dominant negative MetAP2 constitutes a single invention and not a species.

In addition upon election of any of groups 60, 62, further election of the following species is required:

Measuring cell growth or fluorescence emission.

The inventions are distinct, each from each other because of the following reasons:

Inventions (1-9) and (10-67) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein.

The products of groups (1-9) are patentably distinct, because they are drawn to entirely different biochemicals , having different structures.

The methods of groups (10-67) are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species measuring cell growth or fluorescence emission are distinct because they are different methods having different method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

November 02/ 2002